GELATO APF- sodium fluoride gel
Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Active ingredient: **Purpose:**

Fluoride Ion 1.23% ..... Fluoride Treatment Gel
Available from 2.09% Sodium Fluoride and Hydrofluoric Acid.

Indications and usage:

- A stable thixotropic fluoride treatment gel used to help prevent dental decay.
- For Professional Office Use Only. This product is not intended for home or unsupervised consumer use.

Warnings:

- Keep out of reach of children.
- Do not swallow. If product is accidentally swallowed in quantities greater than would normally occur with a treatment gel, seek medical help or contact a Poison Control Center right away.
- Read directions carefully before using.

Dosage and administration:

Shake well before use. This is a one minute or four minute fluoride gel for in-office patient use. It is normally used as a preventative caries treatment twice a year.

1. After thorough prophylaxis, fill two single or one dual tray, one third full with gel. Air dry teeth and insert trays into the mouth.

2. Instruct patient to bite down lightly but firmly for one minute (80% effectiveness) or four minutes (100% effectiveness).

3. Remove trays. Instruct patient to expectorate any excess gel and not to eat or drink for at least 30 minutes.

Inactive ingredients:

Citric Acid, Flavor, Magnesium Aluminum Silicate, Phosphoric Acid, Polysorbate 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, Water, Xantham Gum, Xylitol. May contain blue #1, green #3, red #3, red #40, yellow #5 (tartrazine), yellow #6 as a color additive.

Other information:

- Do not store above 25°C/77°F. Do not freeze.

GELATO APF

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68400-313
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	5.6 g in 454 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	white (Dye Free)	**Score**	
Shape		**Size**	
Flavor	VANILLA	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68400-313-15	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2014	

Labeler - Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.

(014769301)

Establishment

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	manufacture(68400-313) , label(68400-313)

Revised: 4/2024 Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc.